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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,659	05/11/2001	Steven M. Ruben	PZ003P4	5111

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/03/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,659

Applicant(s)

RUBEN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-35 and 56-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-35 and 56-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This Non-Final Office Action is a response to the "Amendment and Response under 37 C.F.R. § 1.116 filed 14 March 2003 (Paper No. 22) in reply to the Final Office Action mailed 18 November 2002 (Paper No. 18). Claims 24-75 were considered in Paper No. 18. Claims 1, 13, 17-19 and 36-55 were canceled in Paper No. 22. Claims 24-35 and 56-75 are pending and under consideration.

Response to Amendment

Rejection of claims 36-55 is rendered moot by cancellation of the claims in Paper No. 22.

Rejection of claims 27, 33 and 56-75 under 35 U.S.C. § 112, first paragraph, as lacking adequate written description is withdrawn in view of the arguments of record in Paper Nos. 20-22.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Upon further consideration, claims 24-35 and 56-75 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are directed to an isolated polypeptide and fragments thereof comprising an amino acid sequence set forth as SEQ ID NO:85. The specification teaches a variety of uses for the claimed polypeptides, and antibodies raised using the polypeptides, including: differential

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identification of tissues or cell types present in a biological sample and diagnosis of diseases and conditions of the reproductive and embryonic systems (page 36). It is asserted therein that expression of the gene at significantly higher or lower levels may be routinely detected in certain tissues or cell types and used to identify individuals having a disorder such as reproductive or embryonic disorders or cancer. However, the utilities set forth do not rise to the requisite level of specific and substantial unless the function of the polypeptide molecule is known or the expression of the polypeptide can be correlated with a specific disease or condition. For example, antibodies raised against a protein that has no known function has no specific utility other than to study the protein; diagnostic or prognostic assays have no utility unless the function, or at least presence or absence of a polypeptide, can be correlated with a pathological state; and a method of treatment or pharmaceutical composition is not useful without knowing what patient population can be treated.

The function of the claimed polypeptides is asserted based on unspecified similarity to preprotachykinin B, which is a member of a group of polypeptides involved in neurotransmission and regulation of smooth muscle tone. However, the art generally acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick *et al.* (2000) *Trends Biotechnol.* 18:34-39 teach that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating specific details of protein function (see Box 2, page 36). Similarly, Bork (2000) *Genome Res.* 10:398-400 teaches that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see

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especially page 399). Smith *et al.* (1997) *Nature Biotechnol.* 15:1222-1223 teaches, “[t]ypical database searching methods are valuable for finding evolutionarily related proteins, but if there are only about 1000 major superfamilies in nature, then most homologs must have different molecular and cellular functions” (second column on page 132). These teaching demonstrate the unpredictability of assigning protein function based on structure alone. Thus, the skilled artisan would not find the asserted function to be credible based on the teachings of the specification. In the absence of a credible function for the claimed polypeptide, the claimed invention lacks a credible utility.

The specification also provides that the claimed polypeptide is primarily expressed in placenta, which is the basis for the asserted utility as a marker for reproductive or embryonic disorders. However, at the time of filing, there was no evidence that the over- or under-expression of the claimed polypeptide in was in any way correlated with a specific pathology. Thus, the asserted utility as a diagnostic amounts to a general statement of diagnostic utility and is not considered a specific utility. Given the lack of a credible function and the absence of a teaching of a specific utility (i.e., a specific disease that could be diagnosed or treated using the claimed polypeptide or antibodies raised against the claimed polypeptide) the polypeptide lacks specific and substantial utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 24-35 and 56-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
March 28, 2003



**JAMES KETTER
PRIMARY EXAMINER**